

Via Email and First Class Mail
October 24, 2008

Joan Gorga, Director
Massachusetts Determination of Need Program
2 Boylston Street, 3rd Floor,
Boston, Massachusetts 02116

Re: DoN Transfers

Dear Ms. Gorga:

Harvard Vanguard Medical Associates, a not-for-profit, tax-exempt medical group that provides care to more than 350,000 adult and pediatric patients at more than 20 offices across eastern Massachusetts, applauds the efforts of the Massachusetts Department of Health (the "Department") to bring additional clarity to the Determination of Need ("DoN") rules with respect to innovative services and new technology (each referred to herein as a "Regulated Service/Technology") implemented either before a DoN was required, or pursuant to a so-called "physician exemption letter." In our view, the Department should be guided by one simple principle: once implemented, a Regulated Service/Technology implemented before a DoN was required or under a physician-exemption letter should be treated the same as a Regulated Service/Technology implemented pursuant to a DoN. No Regulated Service/Technology, nor any provider of the same, should be advantaged or disadvantaged based on the manner of implementation. Each basis for implementing a Regulated Service/Technology (i.e., implementation before a DoN was required, a physician exemption letter, and the standard DoN process) was, at the time, permitted. As a result, all implemented Regulated Services/Technologies stand on the same legal footing. In light of this, therefore, the manner in which a Regulated Service/Technology was implemented should not result in a disparity in the treatment of that implemented Regulated Service/Technology under the regulations to which it is subject to on an ongoing basis.

In this respect, the language in revised 105 CMR 100.246(D) is of particular concern.¹ That provision provides:

No person who, pursuant to [physician exemption letter], acquired medical equipment that is used to provide an innovative service or that is a new technology, for location other than in a health care facility, may implement an addition, expansion, conversion, transfer of site or transfer of ownership of such equipment unless the Department is first notified pursuant to 105 CMR 100.246(D) and **determines there is need therefore**, or unless an exemption is granted pursuant to 105 CMR 100.263. For purposes of review of the addition, expansion, conversion, transfer of site or transfer of ownership of such equipment, the Department shall deem that such equipment was acquired pursuant to a determination of need. (emphasis added)

There is some ambiguity regarding how the Department should interpret the bolded language above (i.e., "determines there is a need therefore"). We think it is imperative that the Department interpret that provision to mean that the "addition, expansion, conversion, transfer of site or transfer of ownership" should be subject to the

¹ 105 CMR 100.246(D) applies to Regulated Services/Technologies implemented pursuant to a physician exemption letter. A substantively identical provision applying to Regulated Services/Technologies implemented prior to a DoN requirement is found in 105 CMR 100.246(C). The comments in this letter apply equally to both sections, but for simplicity's sake this letter focuses on the physician exemption letter provisions.

DoN regulations as if the Regulated Service/Technology were originally implemented pursuant to a DoN. Any other interpretation would plainly contradict the last sentence of the section, which explicitly requires that conclusion. For example, if the Department interpreted the bolded language to mean that a transfer of ownership should be permitted only after an independent assessment of then-current need (and a conclusion that such need exists), this interpretation would be clearly contrary to the last sentence of the section, which provides that: “For purposes of review of [a] transfer of ownership of such equipment, the Department shall deem that such equipment was acquired pursuant to a determination of need.” Because the Department does not require an independent assessment of need to transfer ownership of a Regulated Service/Technology implemented under a DoN, to require such an assessment for a Regulated Service/Technology implemented under a physician exemption letter would be inconsistent with the plain language of the last sentence of 105 CMR 246(D). Moreover, from a health policy perspective, it would impose inequitable regulatory burdens on Regulated Services/Technologies in use and meeting patient needs solely on the basis of their original authorization (i.e., a physician exemption letter, rather than a DoN). We do not believe that there is a sound health policy rational for making such a distinction.

We also urge the Department to confirm that the expansion of a Regulated Service/Technology implemented under a physician exemption letter will be subject to the normal DoN regulations and guidelines regarding expansion of implemented services. Again, any other approach would contradict the last sentence of 105 CMR 100.246(D).

In summary, we strongly encourage the Department to confirm that a Regulated Service/Technology implemented under a physician-exemption letter will be treated the same as a Regulated Service/Technology implemented under a DoN. Regulated Services/Technologies implemented under a physician exemption letter are an important component of the Commonwealth’s health care delivery system. There is no principled basis on which those implemented Regulated Services/Technologies can be or should be distinguished from other equally important health care delivery resources.

We believe that the Department would agree that such a policy of equal treatment of these implemented Regulated Services/Technologies would provide for a uniform set of rules regarding medical equipment and services subject to DoN. Such uniformity would serve the best interests of the Department, regulated providers, and the public that is served by these providers.

Pursuant to the Department’s request, we are also submitting these comments electronically to joan.gorga@state.ma.us. Thank you very much for the opportunity to comment on the Department’s regulations. We very much appreciate the Department’s consideration of our views.

Sincerely,

A handwritten signature in black ink, appearing to read "H. Lindsey, Jr.", with a stylized flourish at the end.

H. Eugene Lindsey, Jr. M.D.
President and Chief Executive Officer